

Amendments to the Specification

Please make the following amendments to the specification:

Please replace the paragraph starting on page 2, line 20 with the following:

--As the ischemic cardiomyopathy progresses, the various structures of the heart are progressively involved including the septum, the apex and the anterolateral wall of the left ventricle. Within a particular wall, the blood starvation begins at the inside of the wall and progresses to the outside of the wall. It can be seen that addressing ischemic cardiomyopathy shortly after the heart attack can limit the detrimental effects to certain elements of the heart structure, as well as the inner most thicknesses of the walls defining those structures.--

Please replace the paragraph starting on page 5, line 7 with the following:

--Although the dilated heart may be capable of sustaining life, it is significantly stressed and rapidly approaches a stage where it can no longer pump blood effectively. In this stage, commonly referred to as congestive heart failure, the heart becomes distended and is generally incapable of pumping blood returning from the lungs. This further results in lung congestion and fatigue. Congestive heart failure is a major cause of death and disability in the United States where approximately 400,000 cases occur annually.--

Please replace the paragraph starting on page 10, line 9 with the following:

-- FIG. 10 is an axial cross section view illustrating a Fontan neck created by the Fontan stitch;--

Please replace the paragraph starting on page 12, line 22 with the following:

-- The heart 12 typically includes four chambers, a right auricle 18, a right ventricle 21, a left auricle 23 and a left ventricle 25. In general, the auricles 18 and 23 are receiving chambers and the ventricles 21 and 25 are pumping chambers. Each of these chambers 18-25 is associated with a respective function of the heart 12. For example, it is the purpose of the right auricle 18 to receive

the deoxygenated blood returning in the veins of the body 10, such as the femoral vein 27. From the right auricle 18, the deoxygenated blood passes into the right ventricle 21 from which it is pumped through a pulmonary artery 30 to the lungs 14 and 16.--

Please replace the paragraph starting on page 15, line 9 with the following:

--The muscles of the body, of course, include the heart muscle or myocardium which defines the various chambers 18-25 of the heart 12. This heart muscle also requires the nutrients and oxygen of the blood in order to remain viable. With reference to FIG. 2, it can be seen that the anterior or front side of the heart 12 receives oxygenated blood through a common artery 58 which bifurcates into a septal artery branch 52, which is directed toward the septum 41, and an anterior descending artery 54 which is directed toward the apex 37 and the lateral ventricle wall 38.--

Please replace the paragraph starting on page 15, line 21 with the following:

--When a blockage occurs in one of these coronary arteries, that portion of the heart muscle which is fed by the blocked artery no longer receives the oxygen needed to remain viable. These blockages typically occur in the common artery 58 and in the septal artery branch 52. When the common artery is involved, the septum 41, apex 37 and lateral wall 38 all become ischemic or oxygen deprived. When only the septal artery branch 52 is involved, the ischemic symptoms are limited primarily to the septum 41 and the apex 37. In this latter case, the septum 41 is almost always affected, the apex 31 is usually affected, and the lateral wall 38 is sometimes affected.--

Please replace the paragraph starting on page 16, line 13 with the following:

--The body's reaction to ischemic infarction is of particular interest. The body 10 seems to realize that with a reduced pumping capacity, the ejection fraction of the heart is automatically reduced. For example, the ejection fraction may drop from a normal sixty percent to perhaps twenty percent. Realizing that the body still requires the same volume of blood for oxygen and nutrition, the body causes its heart to dilate or enlarge in size so that the smaller ejection fraction pumps about the same amount of blood. As noted, a normal heart with a blood capacity of seventy milliliters and an ejection fraction of sixty percent would pump approximately 42 milliliters per beat. The body seems

to appreciate that this same volume per beat can be maintained by an ejection fraction of only thirty-percent if the ventricle 25 enlarges to a capacity of 140 milliliters. This increase in volume, commonly referred to as "remodeling" not only changes the volume of the left ventricle 25, but also its shape. The heart 12 becomes greatly enlarged and the left ventricle 25 becomes more spherical in shape losing its apex 37 as illustrated in FIG. 3. In this view, the stippled area of cross section shows the ischemic or infarcted region of the myocardium.--

Please replace the paragraph starting on page 18, line 15 with the following:

-- The procedure of the present invention addresses the effects of myocardial infarction using a cardioprotective approach to restore the geometry of the left ventricle. This is not a "remodeling" procedure automatically produced by the body 10, nor a "reconstructive" procedure which leaves the heart with other than a normal geometry. Rather, this is a procedure which attempts to "restore" the normal geometry, and particularly the apical configuration of the left ventricle 25. The procedure reduces the volume of the left ventricle 25, but also increases the percentage of the ventricle wall which is viable. This greatly increases the ejection fraction of the heart and significantly reduces heart stress.--

Please replace the paragraph starting on page 21, line 16 with the following:

--The sheet material 81 can have a generally flat planar configuration, or can be shaped as a section of a sphere. The spherical shape can be achieved as illustrated in FIG. 12B by fixing the pericardium while it is stretched over a spherical die to form a concave surface 89.--

Please replace the paragraph starting on page 22, line 11 with the following:

--Many variations on the patch 72 will be apparent from the foregoing discussion. For example, as illustrated in FIG. 17, the sheet material 81 can be provided with a convex surface 95 facing the left ventricle 25 rather than the concave surface illustrated in FIG. 13. As illustrated in Figures 16 and 18, the ring 87 can be disposed on either the interior or exterior side of the material 81.--

Please replace the paragraph starting on page 23, line 1 with the following:

--It will be appreciated that many variations on these preferred embodiments of the patch 72 will be apparent, each having a generally non-circular sheet material, such as the material 81, and perhaps a somewhat flexible toroid or oval ring 87.--

Please replace the paragraph starting on page 23, line 14 with the following:

-- Another method for placement of the interrupted patch suture is illustrated in FIG. 22B. In this view, which is similar to FIG. 21, interrupted sutures 111 are directed through the entire ventricular wall 38 and exit the wall 38 in proximity to the protrusion 76 which forms the Fontan neck 78. These sutures 111 can also be anchored in a pledged strip 113 disposed on the outer surface of the heart 12 to further enhance the anchoring of these sutures 111.--

Please replace the paragraph starting on page 23, line 20 with the following:

--When all of the interrupted sutures 105 have been placed around the circumference of the neck 78, the patch 72 can be moved from its remote location along the sutures 105 and into proximity with the oval neck 78. This step is illustrated in FIG. 22A where the patch 72 is embodied with the concave surface 89 facing the neck 78 and with the ring 87 disposed outwardly of the material 81. After the patch 72 has been moved into an abutting relationship with the neck 78, the interrupted sutures 105 can be tied as illustrated in FIG. 23.--

Please replace the paragraph starting on page 24, line 1 with the following:

--Having closed the left ventricular cavity 25 with the patch 72, one may proceed to address any bleeding which may have resulted from placement of the Fontan stitch 74 or the sutures 105, especially from the region of the septum 41. Such bleeding, illustrated by the reference numeral 112 in FIG. 23, will typically occur in close proximity to the neck 78 and beneath the region covered by the rim or flange 93 associated with the material 81 of the patch 72. This bleeding can normally be stopped by merely placing a suture through the ventricular wall 38 and the rim 93 at the point of

bleeding. A pledget 114 can be used to tie the suture 105 with the rim 93 closely held against the bleeding wall 38. This reinforcing stitch, acting in combination with the rim 93 of the patch 72, will usually stop any bleeding associated with the sutures.--

Please replace the paragraph starting on page 24, line 12 with the following:

--With the patch 72 suitably placed, the operative site can be closed by joining the myocardial walls in a vest-over-pants relationship as illustrated in FIG. 24. Care should be taken not to distort the right ventricle 21 by folding the septum wall 41 over the ventricular wall 38. Alternatively, the lateral wall 38 can be disposed interiorly of the septum wall 41 so a majority of the force on the patch 72 is diverted to the lateral wall 38. These walls 38 and 41 can be overlapped in close proximity to the patch 72 in order to avoid creating any cavity between the patch 72 and the walls 38, 41. When air evacuation is confirmed by transesophageal echo, the patient can be weaned off bypass usually with minimal, if any, inotropic support. Decanulation and closure is routine.--

Please replace the paragraph starting on page 26, line 10 with the following:

--A further advantage of this procedure relates to the incision 61 in the left ventricle 25 which also provides access to the mitral valve 34. Replacing this mitral valve 34 through the left ventricle 25 is much simpler than the present intra-atrial replacement procedure. Coronary artery bypass grafts also can be more easily accommodated intraoperatively. As a result, all of these repairs can be undertaken with greater simplicity and reduced time. While blood cardioplegia may be advantageously used for revascularization and valvular procedures, it would appear that the restorative procedure is best accomplished with continuous perfusion of the beating open heart for cardiac protection.--

Please replace the paragraph starting on page 26, line 19 with the following:

--Placement of patch 72 can be further enhanced by providing in the patch kit a plurality of sizing disks which can be individually held in proximity to the Fontan neck in order to determine appropriate patch size. Similar discs, triangular in shape may be used for the inferior restoration process. The disks might have a generally planar configuration, and of course, would vary in size. Each disk might have a centrally located handle extending from the planar disk for ease of use. The

patch 72 could be removably mounted on a holder also including a disk, on which the patch is mounted, and an elongate handle extending from the disk to facilitate placement.--

Please replace the paragraph starting on page 27, line 22 with the following:

--As the incision is opened and the non-contracting regions 128 on either side are laid back, a line of separation 137 can be located between the non-contracting region 128 and contracting regions designated generally by the reference numeral 140. Basting sutures 142 are placed generally along this line of separation 137. These basting sutures 142 include a base suture which extends between pledgets 146 and 144 along the base 37. Similarly, lateral basting sutures 148 and 157 can be placed to extend along the line of separation 137 between pledgets 153 and 155, and pledgets 151 and 160, respectively. In a preferred orientation, the lateral basting sutures 148 and 157 meet at a basting apex 162 and diverge to individually intersect the basting sutures 142 at the base 37. Thus, the basting sutures 142, 148 and 157 form a triangle along the line of separation 137.--